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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/324,343	06/02/1999	JOHAN H. GEERKE	ALZA-0022 ARC-2865-R3	1409
23377	7590	01/14/2004	EXAMINER	
WOODCOCK WASHBURN LLP ONE LIBERTY PLACE, 46TH FLOOR 1650 MARKET STREET PHILADELPHIA, PA 19103			SHARAREH, SHAHNAM J	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/324,343

Applicant(s)

GEERKE ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 07, 2003 has been entered.

**Status of the Claims**

Applicant had elected with traverse of Group III, claims 18-31 in Paper No. 5 filed on April 24, 2000. The restriction requirement was made pursuant to reasoning on the Paper No. 4 filed on February 12, 2000. Claims 1-17 are withdrawn from further consideration because they are directed to a non-elected invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22-31 rejected under 35 U.S.C. 103(a) as being unpatentable over Hoover et al US Patent 5,464,631 ("Hoover") and Jacobs et al US Patent 5,824,338 ("Jacobs") in view of Wong et al US Patent 5,785,994 ("Wong").

The instant claims are directed to three-layer tablets comprising a first and second layer that contains a drug and at least one colorant, and a third layer containing a second and different colorant. The dependent claim further adds a coating layer to said tablets.

Hoover et al disclose tablet formulations containing a two color partially encapsulated medicament in a caplet form wherein at least one pharmaceutically active material comprise a first colorant, and a second layer which is of a different color (see abstract, col 5 lines 45-52, col 7 lines 8-20). Hoover's capsule/caplet formulation contains a caplet, which is a compressed capsule shaped tablet, encased at least partially with a half-gelatin capsule of different color for aesthetic and recognition

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purposes. (see col 4, lines 1-40). Hoover teaches the use of different coloring agent for identification of different parts of their formulation. Hoovers' teachings meet the limitation of claims 22-24, 27-29.

Further, Hoover disclose methods of producing a two colored caplet wherein said caplet is further coated with a solution consisting of various types of polymers such as polyvinylpyrrolidone or cellulose derivatives (see col 7 lines 39-42). Such teachings meet the limitations of claim 26, 31. Therefore, Hoover et al disclose dosage forms that comprise a first layer containing an active drug with a colorant, second layer which is drug free but of different color, and the third coating layer which comprise film-forming material.

Contrary to Applicant's arguments the teaching of Hoover does is not directed to capsule dosage forms rather providing a tamper resistant and tamper evident caplet dosage forms, which is a tablet. The instant claims do not exclude such formulations disclosed by Hoover. Hoover's formulations are not osmotic tablets containing a port, however, Hoover mentions that his methodology may be used for sustained release formulations by methods known in the art. Such formulations include osmotic tablets (col 5, lines 34-40).

Jacobs' teachings are supplemental to Hoovers. Jacobs is primarily used to indicate the state of art with respect to the use of colorant in making multi layer caplets. According to Jacobs caplet layers such as gelatin coating can be clear or colored in matching or different colors to provide the desired appearance of the resultant medicament to identify the medication contained within the cover and to provide a

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pleasing aesthetic appearance to the medicament (col 1, lines 60-67; col 4 lines 5-10; col 4, lines 53-57).

Wong teaches three-layered osmotic tablets containing a port (see abstract). At least one layer of Wong's tablets contains a dye such as ferric oxide. Wong discloses tablet dosage forms comprising three layers wherein first layer is drug free and is a push layer which contains a colorant such as ferric oxide (see col 17 line 23; col 20, lines 20-25) and the third layer comprise a colorant (see figure 3, col 16 lines 58-67, col 18 lines 1-42). The tablet of Wong comprises an exit port (see col 17 line 56) meeting the limitation of claims 25, 30 (see col 15 lines 15-18). Finally, Wong et al disclose that their tablets are prepared by pressing the three layers to form a solid core (see col 19 lines 10-18).

Although, Hoover does not specifically teach a three layer osmotic dosage form, he suggests that an ordinary skilled in the art may modify his caplet forms to formulate a sustained release dosage form (see col 5 lines 34-44). Therefore, it would have been obvious to one ordinary skilled in the art to modify formulate a sustain dosage forms such as an osmotic tablet as taught by Wong and incorporate a coloring agent in any desired layer for their own intended use and further improve the dectability of each layer formulate a three layer osmotic tablet formulation, because as shown by Hoover and Jacobs the use of colorant in different layers of a caplet formulation for their own intended use is well established in the art.

One of ordinary skill in the art would have had a reasonable expectation to succeed to use colorant in each layer because employing such agents for mere identification purposes is well described in the art as shown by Hoover and Jacobs.

Claims 18-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoover and Jacobs in view of Wong and further in view of Misra et al US Patent 5,422,831 ("Misra").

The teachings of Hoover, Jacobs and Wong are discussed previously. Their combined teachings does not specifically provide for the instant step of using the color for detecting the orientation of the tablet with a color detector.

Misra teaches methods of determining the quality of pharmaceutical products based on physical characteristics such as shape, hardness, color and surface (col 3 lines 29-40) using transducer signals. Misra teaches analysis of the color of the pills and detection of undesirable characteristics of a given dosage form (col 11 lines 5-50, col 13 lines 1-24).

The teachings of Hoover, Jacobs and Wong are not directed to detection of physical characteristics of a dosage form such as a multi layer osmotic caplet, but as discussed above the combined teachings of Hoover, Jacobs and Wong renders the use of colorants in different layers of an osmotic dosage forms obvious.

Since methods of determining color characteristics of dosage forms by a detector, as taught by Misra, are conventional; it would have been obvious to one of ordinary skill in the art at the time of invention to formulate a multi layer osmotic dosage form having different color in each layer, as described by Hoover, Jacob and Wong, and

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further study its physical characteristics as taught by Misra to determine physical characteristic of such caplets including its the orientation of its layers.

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

ss

  
RUSSELL TRAVERS  
PRIMARY EXAMINER